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EXAMINER				
EPPS-SMITH, JANET L.				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/598,597

Applicant(s)

DAVIES ET AL.

Examiner

JANET L. EPPS-SMITH

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/20/2010 has been entered.
2. Claims 1-16 are pending for examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the fifth paragraph of 35 U.S.C. 112:

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

4. Claims 13 and 16 are rejected under 35 U.S.C. 112, 5th paragraph, as being in improper multiple dependent form.
5. Claim 13 recites the process of claim 7. However, claim 7 is a multiple dependent claims that recites dependency from claims 1 to 6. Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall not serve as the basis for another multiple dependent claim. See MPEP § 608.01(n).
6. Claim 16 recites the process of claim 15. However, claim 15 is a multiple dependent claims that recites dependency from claims 1-6. Claim 16 is objected to

under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall not serve as the basis for another multiple dependent claim. See MPEP § 608.01(n).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 2-8 recite "[A] process according to claim 1...." This phrase is vague and indefinite since it is unclear which process Applicants are referring to. Claim 1 recites only one process, the phrase "a process of claim 1," suggests that there are alternative processes set forth in claim 1. In an effort to avoid confusion, Applicants should amend claims 2-8 to recite "[T]he process according to claim 1..."

Response to Arguments

Claim Rejections - 35 USC § 102

10. Claims 1-3, and 8-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Baksh et al. (WO02/086104A1; ¶ numbers cited below are taken from the US patent application 20040137612).

11. Applicant's arguments filed 06/21/2010 have been fully considered but they are not persuasive. Applicants traverse by citing the arguments set forth in the opinion declaration of Dr. Dolores Baksh. First, it is argued that the protocol set forth in the cited reference "would not have been conducted under non-static culture conditions."

(Pages 3-4 of the Baksh Declaration) Since the claims are limited to a method in which cells are cultured under non-static conditions, Applicants argued that the protocol set forth in the prior art does not anticipated the claims.

12. According to the Baksh Declaration, the cited reference "directs the reader to grow the progenitor cells in non-static non-adherent culture in serum-containing medium and to differentiate the progenitor cells in static culture in a serum-deprived medium." The Declaration concludes that "[i]n neither case, does WO02/086104 teach combining serum-deprived medium and non-static culture for growing the progenitors." (Page3, 4th paragraph of the Baksh Declaration)

13. Despite the above analysis of the cited reference. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that combining serum-deprived medium and non-static culture for growing the progenitors) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

14. The instant claims are drawn to a process for culturing a stem and/or progenitor cell population, the claims are not limited to a method for growing the progenitors as asserted by Applicants and as argued in the Declaration by Dr. Baksh.

15. Moreover, in regards to Applicant's assertion that the cited reference does not recite a non-static method, the examiner again refers to ¶[0079] of Baksh et al., which recites: "[F]or differentiation into chondroblasts, the progenitors can be grown in serum-

free DMEM supplemented with TGF- β . in suspension culture, for about 14 days or more."

16. According to the Declaration of Dr. Baksh, a person of ordinary skill in the art would interpret the term "suspension" as used in this context refers only to a non-adherent culture, and does not represent a non-static culture condition." This statement appears to be an opinion, since it is not supported by any specific facts regarding the disclosure of this reference. Contrary to Applicant's assertions, according to paragraphs [0094] through [0098] of Baksh et al., suspension cultures were stirred, i.e. non-static, and that static cultures were also run, however only as controls for the stirred suspension cultures.

17. This passage clearly teaches the use of non-static conditions in a serum-free culture of progenitor cells, and therefore reads on claims 1-3, and 8-11.

18. Furthermore, according to the Declaration of Dr. Baksh, the examiner's interpretation of paragraph [0079] is incorrect because "[T]he stem and/or progenitor cells do not actually grow; they only differentiate." Again, as stated above, the instant claims are drawn to a process for culturing a stem and/or progenitor cell population, the claims are not limited to a method for growing the progenitors as asserted by Applicants and as argued in the Declaration by Dr. Baksh. However, even if the claims were limited to a method involving stem and/or progenitor "growth," the passage of paragraph [0079] clearly states "the progenitors can be grown in serum free DMEM.." The examiner offers no interpretation of this statement. Applicants have not provided

any rationale why one of ordinary skill in the art would not understand this statement, or would interpret it to not mean exactly what it states.

19. The Declaration under 37 CFR 1.132 filed 05/20/2010 is insufficient to overcome the rejection of claims 1-3, and 8-16 based upon Baksh et al. as set forth in the last Office action for the reasons set forth above.

20. Regarding the population of cells recited in claims 9-10, specifically the CD45-/CD123 (IL3+) cells, see Figure 7, and paragraph [0059] of this reference. Figure 7 clearly shows the expansion of CD45- progenitor cells in the presence of CD123 (IL3). Thus, the population represented by Figure 7 reads on the instant claims.

Claim Rejections - 35 USC § 102

21. Claims 1-2, 7-8, 11, and 13-15 remain rejected under 35 U.S.C. 102(a) as being anticipated by Kallos et al. (2003).

22. Applicant's arguments filed 05/20/2010 have been fully considered but they are not persuasive. Applicants traversed the instant rejection in the following manner: "[W]ithout acquiescing in the propriety of this rejection, Applicants point out that the rejection is moot in view of the amendment that incorporates the limitation of claim 3 into claim 1. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested." Contrary to Applicant's assertions, the examiner is unaware of any amendment to claim 1 which incorporates the limitations of claim 3, no such amendment has been made. The claims therefore remain rejection for the reasons of record.

23. Kallos et al. teach a method for the large scale culturing of neural stem cells (NSCs) by non-static, non-adherent suspension in serum-deprived nutrient medium. Kallos teaches the expansion of human and murine NSCs on a large scale in suspension bioreactors in a new serum-free media. (See abstract) Absent evidence to the contrary, the NSCs suspension disclosed in this reference would read on a pharmaceutical formulation.

Claim Rejections - 35 USC § 103

24. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baksh et al. WO 2002/086104 in view of Cancedda et al. (US 6617159).

25. Applicants traversed the instant rejection on the grounds that the culturing conditions of Cancedda et al. included the use of anchorage dependent methods. Contrary to Applicant's assertions, Applicants have not provided any evidence that the medium for expanding mesenchymal cells, as disclosed by this reference is specifically limited only to anchorage dependent culturing conditions.

26. The scope of the claims 4-6 issued in the Cancedda et al. US Patent clearly encompasses a method of "culturing", there are no limitations set forth in the issued claims which would limit the issued method to only anchorage dependent culturing conditions. Furthermore, the product claims drawn to a serum free culture medium, do not appear to be limited to only anchorage dependent methods.

27. Contrary to Applicant's assertions, as stated in the prior Office Action, it would have been obvious to the ordinary skilled artisan to modify the teachings of Baksh et al. with the teachings of Cancedda et al. in the design of the instant invention. One of

ordinary skill in the art would have been motivated to make this modification since Baksh et al. clearly teach that the disclosed methods of culturing should be performed in the presence a medium that was suitable for culturing non-hematopoietic progenitor cells, including mesenchymal progenitor cells, and Cancedda et al. disclose a medium suitable for culturing of mesenchymal stem cells. See MPEP § 2144.06 [R-6], which teaches that it is prima facie obvious for the ordinary skilled artisan to substitute art recognized equivalents known for use in the same purpose.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. EPPS -SMITH whose telephone number is (571)272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633